

BioHorizons Implant Systems, Inc.
510(k) Notification
December 30, 1995

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510(k) Summary of Safety and Effectiveness

Proprietary Name

BioHorizons Dental Implant System (name subject to change)

Common Name

Uncoated, titanium plasma spray, and hydroxyapatite screw-form implants, surgical components, and prosthetic components

Classification Name

Endosseous implants, surgical components, and prosthetic attachments

Classification

Class III

Official Contact

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Device Description

The BioHorizons Dental Implant System is a comprehensive system containing implants, surgical components, and prosthetic components. The implants are specifically designed to optimize strain distribution to contiguous bone under functional loading in order to promote strain-induced bone growth and interface maintenance over the long term. This improvement in biomechanical performance is achieved by optimizing implant designs specifically for each bone density classification (D1, D2, D3, D4) in the mandible and maxilla.

Four implant designs, corresponding to each bone density classification, are available in four and five mm diameters. Each implant design, manufactured from titanium alloy

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conforming to ASTM F 136, is available in two lengths and may feature a glass bead, titanium plasma-spray (TPS), or hydroxyapatite (HA) coating. The following table provides a comprehensive summary of implant diameter, length, and coating.

Diameter (mm)	Design	Lengths (mm)	Coating
φ4.00	D1	10, 12	Glass Bead
	D2	11, 13	TPS
	D3	12, 14	HA
	D4	13, 15	HA
φ5.00	D1	9, 11	Glass Bead
	D2	10, 12	TPS
	D3	11, 13	HA
	D4	12, 14	HA

The body of each implant includes a significant enhancement of the basic screw-form implant macrodesign to optimize the implants for specific regions of the mandible and/or maxillary bone. This objective is accomplished by varying the thread depth and thread form within and between each implant design. Pitch is varied between the four implant designs.

Product Evaluation

Evaluation of the BioHorizons Dental Implant System consisted of (1) closed form calculations, (2) finite element analyses, (3) implant mechanical tests, and (4) bioactive coating mechanical tests. These analyses indicate that the BioHorizons Dental Implant System should be safe and effective when used as intended.

Indications

The BioHorizons Dental Implant System may be used in the mandible and maxilla for use as an artificial root structure for single tooth replacement or as abutments for fixed bridgework and denture retention.

Substantial Equivalence Information

The BioHorizons Dental Implant System is substantially equivalent in all features which could affect safety or effectiveness to the Steri-Oss[®] Hex-Lock (HL) Threaded Titanium Implants and the Branemark System[®] Implants

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